

K961371

JUL 24 1996

17

510(k) Premarket Notification
Subcutaneous Urinary Diversion Stent Set
Cook Urological

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

Tammy Bacon
Cook Urological
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-4891
April 8, 1996

Device

Trade Name:	Subcutaneous Urinary Diversion Stent Set
Proposed Classification Name:	Splint, Ureteral

Predicate Devices:

The Subcutaneous Urinary Diversion Stent Set is comprised of a stent and accessories which are equivalent to predicate devices in terms of indications for use, design, and materials of construction.

Device Description:

The Subcutaneous Urinary Diversion Stent Set and Exchange Set is used to create a new tunnel leading from the renal pelvis to the urinary bladder for the purpose of providing decompression of the renal system. The set contains a stent, dilators, sheaths, wire guides, needle syringe and the exchange set contains a dilator, sheath, positioner, release sleeve and wire guide. This device is intended for one-time use.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program. The device will undergo packaging and sterilization procedures similar to devices currently marketed and distributed by Cook Urological, Inc. This device is similar with respect to indications for use, materials, and physical construction to predicate devices, thereby meeting the requirements for section 510(k) substantial equivalency.